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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/525,819	02/25/2005	Marion Beckmann	033495-020	9184

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EXAMINER

ROBINSON, BINTA M

ART UNIT	PAPER NUMBER
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1625

DATE MAILED: 08/29/2006

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary

Application No.

10/525,819

Applicant(s)

BECKMANN ET AL.

Examiner

Binta M. Robinson

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-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☐ Responsive to communication(s) filed on ____.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1-18 and 20-25 is/are pending in the application.
- 4a) Of the above claim(s) ____ is/are withdrawn from consideration.
- 5) ☐ Claim(s) ____ is/are allowed.
- 6) ☒ Claim(s) 1-18 and 20-25 is/are rejected.
- 7) ☐ Claim(s) ____ is/are objected to.
- 8) ☐ Claim(s) ____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on ____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☒ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☒ All b) ☐ Some * c) ☐ None of:
- ☐ Certified copies of the priority documents have been received.
 - ☐ Certified copies of the priority documents have been received in Application No. ____.
 - ☒ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- | | |
|--|---|
| 1) <input checked="" type="checkbox"/> Notice of References Cited (PTO-892) | 4) <input type="checkbox"/> Interview Summary (PTO-413)
Paper No(s)/Mail Date. ____. |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948) | 5) <input type="checkbox"/> Notice of Informal Patent Application (PTO-152) |
| 3) <input checked="" type="checkbox"/> Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08)
Paper No(s)/Mail Date <u>2/25/05</u> . | 6) <input type="checkbox"/> Other: ____. |

Detailed Action

The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless --

(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

Claim(s) 1,11,15,16, 21,22, and 23 are rejected under 35 U.S.C. 102(b) as being anticipated by Maienfisch et. al. (See Reference N). Maienfisch et. al. discloses the instant compounds, 1.17, 1.21, 1.46, 1.73, 1.77, 1.102, 1.105. At page 20, Table 1, see the instant compounds, 1.17, 1.21, 1.46, 1.73, 1.77, 1.102, 1.105. Compound 1.17 anticipates the instant claims because R2 which is analogous to the instant R5 can be C(=O)CH₃, X is CH, m is 0, R1 which is equivalent to the instant R4 is 4-chlorophenyl. Compound 1.21 anticipates the claims because R2 which is analogous to the instant R5 can be C(=O)CH₃, X is CH, m is 0, R1 which is equivalent to the instant R4 is 3,4 dichlorophenyl. Compound 1.46 anticipates the instant claims because R2 which is analogous to the instant R5 can be C(=O)CH₃, X is CH, m is 0, R1 is 4-flourophenyl. Compound 1.49 anticipates the instant compounds, because R2 which is analogous to the instant R5 can be C(=O)CH₃, X is CH, m is 0, R1 is 3,5-dichlorophenyl. Compound 1.73 anticipates the instant compounds, because R2 which is analogous to the instant R5 can be C(=O)CH₃, X is N, m is 0, R1 is 4-flourophenyl. Compound 1.77 anticipates the instant compounds because anticipates because R2 which is analogous to the instant R5 can be C(=O)CH₃, X is N, m is 0, R1 which is equivalent to the instant R4 is

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3,4 dichlorophenyl. Compound 1.102 anticipates the instant compound because R2 is which is analogous to the instant R5 can be C(=O)CH3, R1 is 4-fluorophenyl, m is 0, X is N.

Compound 1.105 anticipates the instant claims, because R2 which is analogous to the instant R5 is C(=O)CH3, R1 which is analogous to the instant R4 is 3,5-dichlorophenyl, X is N, and m is 0.

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

Claims 1-18, 20, 21, 22, 23 are rejected under 35 U.S.C. 103(a) as being unpatentable over Maiefisch. (See Reference N).

Maiefisch et. al. teaches the instant compound as shown in Formula I, wherein R1 can be C1-C4 alkyl, C3-C8-cycloalkyl, C3-C6-alkenyl, C3-C6 alkynyl; or C1-C6 alkyl, C3-C6-alkenyl or C3-C alkyl, C3-C6 alkenyl or C3-C6 alkynyl, which are substituted by one or more substituents selected from the group consisting of halogen, nitro, cyano, -OH, -SH, C3-C8-Cycloalkyl, halogen-C3-C8Cycloalkyl, C1-C6-alkoxy, halogen-C1-C6 alkoxy, C3-C6 alkenyloxy, C1-C4-alkylthio, C1-C4-alkyl)amino, -C(=O)R4, wherein R4 is C1-C8 alkyl, R2 can be hydrogen, C1-6 alkyl, C3-6 alkenyl, C3-6 alkynyl, C1-6alkyl, which is mono- to trisubstituted by substituents selected from the group consisting of halogen,

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cyano, C1-C2alkoxy, halogen-C1-C2-alkoxy, di(C1-C2alkyl)amine, -C(=O)R₄, wherein R₄ is C1-C4 alkyl and a method of preparing said compound of formula I by reacting a compound of formula III with a compound of formula IV in order to produce a compound of formula I, and a method for controlling pests when the Maiefisch compound is applied to the pests or their habitat. At page 4, lines 28-30 and at page 5, lines 1-2, lines 23-27, and page a7, lines 1-8, see the Maiefisch process, and at page 27, claim 7, see the method of controlling pests. The difference between the prior art compound and process and the instantly claimed compounds and process is the teaching of a generic compound versus a disclosed species. It would have been obvious to one of ordinary skill in the art to select various known radicals within a genus to prepare structurally similar compounds and to use these compounds for controlling pests. For instance, see the compound, 1.17, where a disclosed species is exemplified and is disclosed as pesticidal. Accordingly, the compounds, the process of preparing them, and using them is deemed unpatentable therefrom in the absence of a showing of unexpected results for the claimed compounds, process of making these compounds, and a method of using these compounds to control pests over those of the generic prior art compounds process of preparing these compounds, and process of using these compounds.

The following is a quotation of the first paragraph of 35 U.S.C. 112:

The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

Claims 1-9, 11, 12, 13, 14, 15, 16, 17, 19, 20, 21, 22, 23, 24, 25 are rejected under 35 U.S.C. 112, first paragraph, because the specification, while being

enabling for using the compounds of formula I with X is CH and R4 equal to substituted C(O)pyridyl, C(O)phenyl, H, C(O)cyclopropyl, acetyl, -C(O)CH=CH₃, R5 equal to -C(O)phenyl, acetyl, -COCH=CH-CH₃, -CO-tert-butyl, -CO(2-chlorophenyl), -CO(2-chloro-4-fluorophenyl), -CO(2-methoxyphenyl), -COCH₂OC₆H₅, -COCH(CH₃)₂, and (C1-C5 alkyl), does not reasonably provide enablement for using the compounds with X is N, or R4 and R5 equal to any of the other moieties claimed. The specification does not enable any skilled artisan to use the invention commensurate in scope with these claims. The factors to be considered in making an enablement rejection have been summarized above.

a) Determining if any particular claimed compounds of formula I wherein X is N, R4 is any claimed moiety other than substituted C(O)pyridyl, C(O)phenyl, H, C(O)cyclopropyl, acetyl, -C(O)CH=CH₃ and R5 is equal to any claimed moiety other than to -C(O)phenyl, acetyl, -COCH=CH-CH₃, -CO-tert-butyl, -CO(2-chlorophenyl), -CO(2-chloro-4-fluorophenyl), -CO(2-methoxyphenyl), -COCH₂OC₆H₅, -COCH(CH₃)₂, and (C1-C5 alkyl), would be active, would require synthesis of the substrate and subjecting it to testing with Applicants' biological activity assay. Considering the large number of compounds to be made, this is a large quantity of experimentation. b) The direction concerning the claimed compounds is found in lines 1-5, page 36, Example 1, and Table 1, page

37, lines 1-8, which merely states Applicants' intent to make and use such compounds. c) In the instant case, none of the working examples contains any radical X equal to N or R4 equal to any of the other radicals claimed other than substituted C(O)pyridyl, C(O)phenyl, H, C(O)cyclopropyl, acetyl, -C(O)CH=CH₃, or R5 equal to any of the other radicals claimed other than -C(O)phenyl, acetyl, -COCH=CH-CH₃, -CO-tert-butyl, -CO(2-chlorophenyl), -CO(2-chloro-4-fluorophenyl), -CO(2-methoxyphenyl), -COCH₂OC₆H₅, -COCH(CH₃)₂, and (C1-C5 alkyl).

d) The nature of the invention is controlling pests using the instant compounds. The nature of the invention requires an understanding of the binding activity of ligands to pests. In view of the unpredictability of binding activity of these ligands and the claimed divergent substituents with varied polarity, size, and polarisability, the skilled person in the art would indeed question the inclusion of such diverse rings and other chemical moieties, commensurate in scope with these claims. Also see the MPEP § 2164.03 for enablement requirements in the structure sensitive arts of pharmacology and medicinal chemistry.

e) There is no reasonable basis for the assumption that the myriad of compounds embraced the present formula (I) will all share the same biological properties. For example, the diverse claimed heteroaryl, carbocyclic aryl and

nonaryl rings and other nonring moieties are chemically non-equivalent and there is no basis in the prior art for assuming in that structurally dissimilar compounds will have such activity. *In re Fouche*, 169 USPQ 429 at 434 (a Markush group including both aliphatic and heterocyclic members not enabled for the use of those compounds within the claim having heterocyclic moieties.) *In re CAVALLITO AND GRAY*, 127 USPQ 202 (claims covering several hundred thousand possible compounds, of which only thirty are specifically identified in appellants' application, not enabled unless all of the thirty specific compounds disclosed had equal hypotensive potency because that fact would strongly indicate that the potency was derived solely from the basic structural formula common to all of them. A wide variation in such potency would suggest that it was due in part to the added substituents and might be eliminated or even reversed by many of the possible substituents which had not been tried.)

f) One of ordinary skill in the art would be unaware of how to predict *a priori* how, for example, changing a heterocyclic ring, a carbocyclic aryl ring, a cycloalkyl ring, or a non-ring moiety would affect biological activity. In view of the divergent rings with varied basicity, steric hindrance, and polarisability as well as the various non-ring moieties claimed, the skilled physician would indeed question the inclusion of such rings, and non-ring moieties commensurate in scope

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with these claims. g) Physiological activity, is well-known to be unpredictable, *In re Fisher*, 427 F.2d 833, 839, 166 USPQ 18, 24 (CCPA 1970) (contrasting mechanical and electrical elements with chemical reactions and physiological activity). See also *In re Wright*, 999 F.2d 1557, 1562, 27 USPQ2d 1510, 1513 (Fed. Cir. 1993); *In re Vaeck*, 947 F.2d 488, 496, 20 USPQ2d 1438, 1445 (Fed. Cir. 1991). h) The breadth of the claims includes all of millions of compounds of formula (I). Thus, the scope is very broad. The present claims embrace various heterocyclic and carbocyclic radicals and non-ring radicals, which are not art-recognized as equivalent. The specific compounds made are not adequately representative of the compounds embraced by the extensive Markush groups instantly claimed.

MPEP 2164.01(a) states, "A conclusion of lack of enablement means that, based on the evidence regarding each of the above factors, the specification, at the time the application was filed, would not have taught one skilled in the art how to make and/or use the full scope of the claimed invention without undue experimentation. *In re Wright*, 999 F.2d 1557, 1562, 27 USPQ2d 1510, 1513 (Fed. Cir. 1993)." That conclusion is clearly justified here. Thus, undue experimentation will be required to practice Applicants' invention.

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Any inquiry concerning this communication or earlier communications from the examiner should be directed to Binta M. Robinson whose telephone number is (571) 272-0692. The examiner can normally be reached on M-F (9:30-6:00).

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Dr. Thomas McKenzie can be reached on 571-272-0670.

A facsimile center has been established. The hours of operation are Monday through Friday, 8:45 AM to 4:45 PM. The telecopier numbers for accessing the facsimile machine are (703)308-4242, (703)305-3592, and (703)305-3014.

Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the receptionist whose telephone number is (571)-272-1600.

BMR
August 8, 2006


THOMAS MCKENZIE, PH.D.
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